UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
(609) 989-2040

CHAMBERS OF
TONIANNE J. BONGIOVANNI
UNITED STATES MAGISTRATE JUDGE

U.S. COURTHOUSE
402 E. STATE STREET, RM 6052
TRENTON, NJ 08608

August 25, 2011

LETTER OPINION AND ORDER

Re: Medeva Pharma Suisse A.G., et al. v. Roxane Laboratories, Inc.
Civil Action No. 07-5165 (FLW)

Dear Counsel:

Pending before the Court is Plaintiffs Medeva Pharma Suisse A.G., Warner Chilcott Company, LLC, and Warner Chilcott (US) LLC's (collectively, "Medeva") application to modify the Discovery Confidentiality Order (the "DCO") [Docket Entry No. 31] entered in this matter on May 21, 2008 at the request of the parties. Specifically, Medeva requests permission to submit, or require Defendant Roxane Laboratories, Inc. ("Roxane") to submit, various expert reports and *in vivo* testing generated by Roxane in connection with this litigation to the Food and Drug Administration (the "FDA"). This information includes:

1. The expert report of Dr. Erik Sandefer, dated December 21, 2009 and all associated exhibits;

2. The expert report of Dr. Larry Augsburger, dated December 21, 2009 and all associated exhibits;

3. The expert report of Dr. Alan Safdi, dated December 21, 2009 and all associated exhibits;

4. The expert report of Dr. Carmello Cuffari, dated December 21, 2009 and all associated exhibits; and

5. Roxane's protocol for A Scintigraphic Evaluation of a Radiolabeled and Non-Radiolabeled Delayed Release Mesalamine (DRM) Formulation in Healthy Male Subjects, dated February 10, 2010.

The Court has reviewed all arguments made in support of and in opposition to Medeva's request.[1] For the reasons stated below, Medeva's request to modify the DCO is DENIED.

I. Background and Procedural History

The Court first addressed Medeva's request to make the aforementioned modification to the DCO in its Letter Order dated July 8, 2008 (the "July 8th Order") [Docket Entry No. 161] in which It denied Medeva's request. The July 8th Order was vacated by the District Court's Opinion and Order dated January 24, 2011 (the "January 24th Order"). In the January 24th Order, the District Court found that it was "unclear what standard the [undersigned] applied in denying [Medeva's] request for modification of the DCO." (January 24th Order at 7; Docket Entry No. 220]. As a result, the District Court vacated the July 8th Order and remanded the issue concerning Medeva's request to modify the DCO "for further consideration with instructions to not apply the burden shifting or compelling need tests and, instead, to apply the entirety of the Third Circuit's balancing test." (*Id.*)

After the District Court entered the January 24th Order, the parties submitted additional correspondence regarding Medeva's request to modify the DCO. The Court reviewed same and after considering all arguments made in support of and in opposition to Medeva's request, determined that, under the Third Circuit's balancing test, modification of the DCO was not warranted. However, the Court did not enter an order to that effect. Instead, in an effort to efficiently and economically resolve the parties' dispute, the Court informally relayed Its decision

[1]This includes arguments made in connection with Medeva's initial request for modification, as well as those made in connection with Medeva's appeals and those made after the appeals (effectual or not) were filed.

to counsel via e-mail and while not explicitly saying so, the Court anticipated that Medeva would seek a formal order should it be deemed necessary. Instead, Medeva filed an appeal of the Court's informal decision denying its request. The Court struck that appeal, finding that it was unviable because no order was entered denying Medeva's request to modify the DCO and, as such, there was no appealable decision of the Court. (*See* 7/11/11 Letter Order (the "July 11th Order") at 2; Docket Entry No. 248]. The Court also informed the parties that it would enter an order reflecting the Court's decision on Medeva's request to modify the DCO. (*See id.*)

II. Discussion

A. Standard of Review

As the District Court made clear in the January 24th Order, "'The appropriate approach in considering motions to modify confidentiality orders is to use the same balancing test that is used in determining whether to grant such orders in the first instance, with one difference: one of the factors the court should consider in determining whether to modify the order is the reliance by the original parties on the confidentiality order.'" (January 24th Order at 6 (quoting *Pansy v. Borough of Stroudsburg,* 23 F.3d 772, 790 (3d Cir. 1994))). These additional factors include:

> (1) whether disclosure will violate any privacy interests; (2) whether the information is being sought for a legitimate or an improper purpose; (3) whether disclosure of the information will cause a party embarrassment; (4) whether confidentiality is being sought over information important to public health and safety; (5) whether the sharing of information among litigants will promote fairness and efficiency; (6) whether a party benefitting from the order of confidentiality is a public entity or official; and (7) whether the case involves issues important to the public.

(*Id*. (citing *Glenmede Trust Co. v. Thompson*, 56 F.3d 476, 483 (3d Cir. 1995)). The Court finds that on balance these factors militate against permitting the requested modification.

B. Analysis

As the Court previously determined, Roxane has a legitimate privacy interest in the aforementioned expert reports and *in vivo* testing. Said documents describe Roxane's confidential tablet formulations and research techniques and also include proprietary data relating to Roxane's research and development work. Further, as the Court also initially found, the expert reports and *in vivo* testing do not represent bioequivalence studies. Contrary to Medeva's arguments, the expert reports and *in vivo* testing were not designed to show the bioequivalence of Roxane's ANDA product with respect to Medeva's patented ASACOL product; instead, the expert reports and *in vivo* testing were generated as part of this litigation for the purpose of demonstrating non-infringement of Medeva's patent. As a result, while Medeva argues that it seeks the modification of the DCO so that it can share information that "may confirm [the] FDA's bioequivalence determination and contradict arguments Roxane currently is making to [the] FDA[,]" the Court finds that disclosing the aforementioned expert reports and *in vivo* testing would not serve this legitimate purpose because the documents were not designed to show bioequivalence. (Medeva Br. at 4; Docket Entry No. 234-1).

Further, while the disclosure of the expert reports and *in vivo* testing would not "embarrass" Roxane, their dissemination, even if solely to the FDA, may very well work a competitive harm to Roxane. This is true because under the applicable FDA regulations, Roxane is not obligated to disclose the aforementioned expert reports and *in vivo* testing, which the Court has determined were not designed to show bioequivalence, to the FDA. *See* 21 C.F.R. § 320.21(b)(1). Requiring Roxane to disclose testing beyond that required by the FDA's own regulations or specifically requested by the FDA would be exceedingly unfair and could unjustly delay the FDA's review of Roxane's ANDA product and increase Roxane's costs in attempting

to gain FDA approval. Moreover, even if the expert reports and testing are confidentially disclosed to the FDA and none of Roxane's other competitors, Medeva, a competitor of Roxane's who, as Roxane's adversary in this litigation, obviously has access to the expert reports and *in vivo* testing generated in this matter, could potentially use the disclosure of same to their advantage and Roxane's detriment.

In addition, while the expert reports and *in vivo* studies at issue here relate to a pharmaceutical drug that may be approved for human consumption, the Court finds that the information contained therein does not strongly impact public health and safety concerns. The Court reaches this conclusion because, before Roxane's ANDA product can become available for mass consumption, the FDA must approve same. While the Court appreciates Medeva's concern that the FDA be fully informed, the Court finds that the FDA is capable of deciding what information it needs to determine whether a drug product should be approved for human use. The Court has already determined that the expert reports and *in vivo* testing are not bioequivalence studies and need not be disclosed under the FDA's regulations. While every test involving a drug product may be determined to be of some importance to public heath and safety, the Court is unpersuaded that Roxane's privacy interest is overridden by the public health and safety concerns raised by Medeva.

The Court also notes that, here, the Court is not faced with the question of sharing information among litigants. Instead, all of the parties in this matter have access to the expert reports and *in vivo* testing in question. Here, Medeva seeks to modify the DCO to permit sharing information with the FDA, a non-party entity. For the reasons already described above, the Court finds that sharing Roxane's confidential expert reports and *in vivo* testing generated in this

litigation with the FDA will not promote fairness. The Court also finds that it will not increase efficiencies either.

The Court additionally notes that Roxane, the party benefitting from the DCO is neither a public entity nor official. Further the Court finds that while this case involves issues that have some importance to the public, including the public's interest in ensuring the bioequivalence of generic drugs, these interests will not be advanced by disclosing Roxane's confidential expert reports and *in vivo* testing to the FDA.

In sum, when the *Glenmede* factors are considered in conjunction with Roxane's reliance on the DCO, they weigh in favor of maintaining the confidentiality of Roxane's expert reports and *in vivo* testing. Indeed, the Court finds that Roxane has met its burden of establishing good cause for the continued protection of its expert reports and *in vivo* testing under the DCO. As a result, Medeva's request to modify the DCO to permit disclosure of Roxane's expert reports and *in vivo* testing to the FDA is denied.

III. Conclusion

For the reasons stated above, Medeva's request to modify the DCO to permit disclosure of Roxane's expert reports and *in vivo* testing is DENIED.

IT IS SO ORDERED.

s/ Tonianne J. Bongiovanni
TONIANNE J. BONGIOVANNI
United States Magistrate Judge